

REMARKS

Claims 1-12, 14-75, 84, 87-104, 106-112 and 127-129 are pending. Claims 4-9, 96-97 and 99-100 have been canceled. Claims 1, 84, 88-93, 98, 106 and 110 have been amended. Claims 130-141 are new. Support for the amendments and the new claims can be found, for example, in Examples 12, 16, 19, 22 and 24, page 111, lines 7-21, page 116, lines 22-25. No new matter is being introduced. Upon entry of these amendments, claims 1-3, 10-12, 14-75, 84, 87-95, 98, 101-104, 106-112 and 127-141 will be pending.

Specification

The specification has been amended to correct the typographical error noted by the Examiner.

Claim Rejections Under 35 USC §112

Claim 93 has been amended as suggested by the Examiner. Applicants therefore respectfully request this ground of rejection be withdrawn.

Claim Rejections Under 35 USC § 103(a)

Claims 1-6, 10, 14, 17-21, 75, 84, 87-99, 102, 106-112 and 127-129 have been rejected by the Examiner as unpatentable over Wallace et al. (U.S. 6,312,725) in view of Shih (U.S. 6,287,588).

Applicants respectively traverse because no sufficient suggestion or motivation has been provided in the Office Action to arrive at amended claim 1. Claim 1, as amended, is directed to a gel-forming composition comprising multiple components including a hydrophobic drug being incorporated in polymeric microspheres, a first component containing Core₁-(SH)_m (wherein Core₁ is polyethylene glycol) and a second component containing Core₂-Y_n (wherein Core₂ is polyethylene glycol and Y is a sulfhydryl reactive group), wherein $m \geq 2$ and $n \geq 2$, and wherein sulfhydryl and Y can form covalent bonds to provide a gel. The resulting gel is hydrophilic due to the polyethylene glycol (PEG) content, yet is compatible with carrying and releasing a hydrophobic drug. These features are not rendered obviousness by Wallace and Shih.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must not be based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ 1438 (Fed. Cir. 1991). *See*, MPEP § 2143.

In the instant case, no sufficient suggestion or motivation has been provided in the Office Action to arrive at amended claim 1. Wallace does not disclose or suggest hydrophobic drugs (or hydrophobic drug incorporated in polymeric microspheres). Instead, Wallace describes combining a crosslinked hydrogel and biologically active agents. The biologically active agents include proteins, carbohydrates and nucleic acids (see, col. 10, line 65), which are primarily hydrophilic agents and are expected to be compatible with Wallace's hydrophilic gel. Accordingly, Wallace does not provide any teaching or suggestion that hydrophobic drugs can be incorporated into the hydrophilic gels. Shih describes an entirely different polymeric gel system from that of Wallace. Shih's polymeric gels are amphiphilic block copolymers containing hydrophobic blocks, in which hydrophobic drugs can be suspended. This characteristic was emphasized in Shih as being advantageous in suspending and wetting hydrophobic particles (*see, e.g.,* Shih, col. 8, lines 1-11). Thus, Shih's teaching is limited to suggesting the compatibility of hydrophobic particles and amphiphilic copolymers having hydrophobic blocks.

Accordingly, there is insufficient motivation or suggestion in Wallace and Shih to make the claimed combination, *i.e.*, combining hydrophobic drugs with a hydrophilic gel. The Examiner's conclusion of obviousness is based on improper hindsight reasoning. It was the Applicants who discovered that hydrophobic drugs (when incorporated into polymeric microspheres) can be formulated into fast-gelling, hydrophilic gels based on crosslinked polyethylene-glycol to form a stable drug-delivery system. These features were not within the knowledge of one skilled in the art at the time of the claimed invention was made. In conclusion, the Applicants submit that a *prima facie* case of obviousness has not been established. Accordingly, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. 103(a).

Applicants believe that all of the claims remaining in the application are now allowable. Claims 11-12, 15-16, 22-74, 92, 101 and 103 have been withdrawn as being directed to non-elected species. Applicants respectfully request that the Examiner continue with the examination of these claims.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (206) 622-4900 to resolve the same.

Respectfully submitted,
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